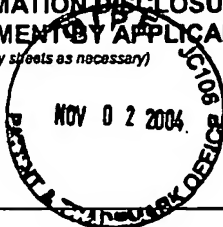


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First Named Inventor	Klimberg, V. Suzanne
Group Art Unit	1614
Examiner Name	Weddington, Kevin

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Attorney Docket No: 781.020US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
W	US-5,438,075	08/01/1995	Skubitz, , et al.			
W	US-5,545,668	08/13/1996	Skubitz, Keith M., et al.	514	561	11/17/1994
W	US-5,658,895	08/19/1997	Aoi, S. , et al.	514	58	06/06/1995

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

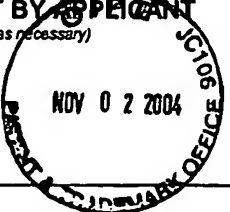
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W		ABCOUWER, S F., et al., "Glutamine deprivation induces the expression of GADD45 and GADD153 primarily by mRNA stabilization", <u>Journal of Biological Chemistry</u> , 274(40), (October 1, 1999), 28645-28651	
		ANDERSON, P M., et al., "Effect of low-dose oral glutamine on painful stomatitis during bone marrow transplantation", <u>Bone Marrow Transplant</u> , 22 (4), (August 1998), 339-344	
		ANDERSON, P. , et al., "Oral glutamine reduces the duration and severity of stomatitis after cytotoxic cancer chemotherapy", <u>Cancer</u> , 83 (7), (October 1, 1998), 1433-1439	
		AYALA, E , et al., "Effect of L-lysine monohydrochloride on cutaneous herpes simplex virus in the guinea pig", <u>Journal of Medical Virology</u> , 28(1), (May 1989), 16-20	
		BASLOW, M. H., et al., "Analysis of the nature of the metabolic lesions responsible for development of the observed clinical symptoms", <u>Journal of Molecular Neuroscience</u> , 9(2), (October 1997), 109-125	
		BINES, J. , et al., "Reducing parenteral requirement in children with short bowel syndrome: impact of an amino acid-based complete infant formula", <u>Journal of Pediatric Gastroenterology & Nutrition</u> , 26(2), (February 1998), 123-128	
		CAO, Y , et al., "Effect of 7,12-dimethylbenz[a]anthracene (DMBA) on gut glutathione metabolism", <u>Journal of Surgical Research</u> , 100(1), (September 2001), 135-140	
		CAO, Y. , et al., "Glutamine enhances gut glutathione production", <u>Jpen: Journal of Parenteral & Enteral Nutrition</u> , 22(4), (July-August 1998), 224-227	
		CARDONA, P. , "Administration of glutamine and its dipeptides in parenteral nutrition. Which patients are candidates?", <u>Nutricion Hospitalaria</u> , 13(1), (January-February 1998), 8-20	
W		FAHR, M. , et al., "Vars Research Award. Glutamine enhances immunoregulation of tumor growth.", <u>Jpen: Journal of Parenteral & Enteral Nutrition</u> , 18(6), (November-December 1994), 471-476	

EXAMINER

W. Weddington

DATE CONSIDERED

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: left; font-size: small;">Complete If Known</td> </tr> <tr> <td style="width: 50%;">Application Number</td> <td>10/633,402</td> </tr> <tr> <td>Filing Date</td> <td>August 1, 2003</td> </tr> <tr> <td>First Named Inventor</td> <td>Klimberg, V. Suzanne</td> </tr> <tr> <td>Group Art Unit</td> <td>1614</td> </tr> <tr> <td>Examiner Name</td> <td>Weddington, Kevin</td> </tr> </table>	Complete If Known		Application Number	10/633,402	Filing Date	August 1, 2003	First Named Inventor	Klimberg, V. Suzanne	Group Art Unit	1614	Examiner Name	Weddington, Kevin
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KW		FENG, ZULIANG, et al., "Glutamine prevents DMBA-induced breast cancer growth", <u>Surgical Forum</u> , 47(0), (1996), 524-526	
		GUERRANT, R L., et al., "Cryptosporidiosis: an emerging, highly infectious threat", <u>Emerging Infectious Diseases</u> , 3(1), (January-March 1997), 51-57	
		JUHL, J. H., et al., "Fibromyalgia and the serotonin pathway", <u>Alternative Medicine Review</u> , 3(5), (October 1998), 367-375	
		KARINCH, A M., et al., "Glutamine metabolism in sepsis and infection", <u>Journal of Nutrition</u> , 131(9 Suppl), (September 2001), 2535S-2577S	
		KLIMBERG, V S., et al., "Glutamine facilitates chemotherapy while reducing toxicity", <u>Jpn: Journal of Parenteral & Enteral Nutrition</u> , 16(6 Suppl), (November-December 1992), 83S-87S	
		KLIMBERG, V S., et al., "Glutamine suppresses PGE2 synthesis and breast cancer growth", <u>Journal of Surgical Research</u> , 63(1), (June 1996), 293-297	
KW		KLIMBERG, V S., et al., "Honorary Lectureship. Glutamine, cancer, and its therapy", <u>American Journal of Surgery</u> , 172(5), (November 1996), 418-424	
		LABOW, B I., et al., "Glutamine", <u>World Journal of Surgery</u> , 24(12), (December 2000), 1503-1513	
		MASTROIACOVO, P., et al., "Amino acids for dialysis patients", <u>Clinical Therapeutics</u> , 15(4), (July-August 1993), 698-704	
		NEU, J, et al., "Enteral glutamine supplementation for very low birth weight infants decreases morbidity", <u>Journal of Pediatrics</u> , 131(5), (November 1997), 691-699	
		OBRADOR, E, et al., "Glutamine potentiates TNF-alpha-induced tumor cytotoxicity", <u>Free Radical Biology & Medicine</u> , 31(5), (September 1, 2001), 642-650	
		PICCIRILLO, N, et al., "Glutamine-enriched parenteral nutrition after autologous peripheral blood stem cell transplantation: effects on immune reconstitution and mucositis", <u>Haematologica</u> , 88(2), (February 2003), 192-200	
		ROUSE, K, et al., "Glutamine enhances selectivity of chemotherapy through changes in glutathione metabolism", <u>Annals of Surgery</u> , 221(4), (April 1995), 420-426	
		SKUBITZ, K M., et al., "Oral glutamine to prevent chemotherapy induced stomatitis: a pilot study", <u>Journal of Laboratory & Clinical Medicine</u> , 127(2), (February 1996), 223-228	
		TSAI, G, et al., "D-serine added to antipsychotics for the treatment of schizophrenia", <u>Biological Psychiatry</u> , 44(11), (December 1, 1998), 1081-1089	
Ka		WU, G, et al., "Dietary glutamine supplementation prevents jejunal atrophy in weaned pigs", <u>Journal of Nutrition</u> , 126(10), (October 1996), 2578-2584	

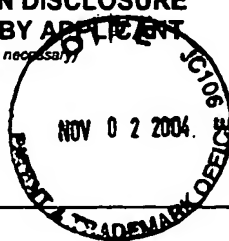
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Attorney Docket No: 781.020US1

W	YAQOUB, P. , et al., "Cytokine production by human peripheral blood mononuclear cells: differential sensitivity to glutamine availability", <u>Cytokine</u> , 10(10), (October 1998), 790-794	
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40-6

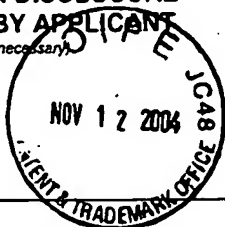
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Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
W	US-2,283,817	05/19/2042	Martin, G. J., et al.	167	55	05/24/1941
	US-2,868,693	01/13/1959	Shive, W., et al.	167	55	07/16/1956
	US-4,857,555	08/15/1989	Smith, R. J.	514	563	09/12/1986
	US-5,039,704	08/13/1991	Smith, R. J., et al.	514	563	10/24/1988
	US-5,366,723	11/22/1994	Tulok, I.	424	10	03/05/1993
	US-5,397,803	03/14/1995	Smith, Robert J., et al.	514	563	04/26/1993
	US-5,607,975	03/04/1997	Smith, Robert J., et al.	514	563	05/07/1996
	US-5,684,045	11/04/1997	Smith, Robert J., et al.	514	563	05/07/1996
W	US-5,763,485	06/09/1998	Smith, Robert J., et al.	514	563	03/13/1995

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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W		ALVERDY, J C., "Effects of Glutamine-Supplemented Diets on Immunology of the Gut", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(4) (Supp), (1990),109S-113S	
		ALVERDY, J C., "Parenteral Nutrition Results in Bacterial Translocation from the Gut and Death Following Chemotherapy", <u>14th Clinical Congress Abstracts</u> , 14 (1)(Supp), (1990), Page 8S	
		AMERICAN COLLEGE OF PHYSICIANS, "Parenteral Nutrition in Patients Receiving Cancer Chemotherapy", <u>Annals of Internal Medicine</u> , 110(9), (1989), 734-736	
		BROWN, M G., "Glutamine-enhanced Enteral Diet Improves Nitrogen Balance Without Increasing Portal Ammonia", <u>British Journal of Surgery</u> , 78(11), (1991),1305-1306	
		BURKE, D J., "Effect of Route of Glutamine Administration GM Mortality Following Experimental Enterocolitis", <u>14th Clinical Congress Abstracts</u> , 14(1) (Supp), (1991),1 Page	
		BURKE, D. J., "Glutamine-Supplemented Total Parenteral Nutrition Improves Gut Immune Function", <u>Archives of Surgery</u> , 124(12), (1989),1396-9	
		DECHELOTTE, P., "Absorption and Metabolic Effects of Enterally Administered Glutamine in Humans", <u>Journal of Physiology</u> , 260(5)(Pt 1), (1991),G677-G682	
		DEFERRARI, G., "Splanchnic Exchange of Amino Acids After Amino Acid Ingestion in Patients with Chronic Renal Insufficiency", <u>American Journal of Clinical Nutrition</u> , 48(1), (1988),72-83	
W		EVANS, M. A., "Intestinal Fuels: Glutamine, Short-Chain Fatty Acids, and Dietary Fiber", <u>Journal of the American Dietetic Association</u> , 92(10), (1992),1239-1246	

EXAMINER

W. Weddington

DATE CONSIDERED

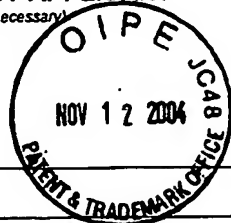
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ICW		FISCHER, J. E., "Adjuvant Parenteral Nutrition in the Patient with Cancer", <u>Surgery</u> , 96(3), (1984), 578-580	
		FISCHER, J. E., "Total Parenteral Nutrition, Glutamine, and Tumor Growth", <u>Jpn: Journal of Parenteral & Enteral Nutrition</u> , 14(4) (Supp), (1990), 86S-88S	
		FONG, Y. M., "Total Parenteral Nutrition and Bowel Rest Modify the Metabolic Response to Endotoxin in Humans", <u>Annals of Surgery</u> , 210(4), (1989), 449-457	
		FOX, A. D., "Effect of a Glutamine-Supplemented Enteral Diet on Methotrexate-Induced Enterocolitis", <u>Journal of Parenteral & Enteral Nutrition</u> , 12(4), (1988), 325-331	
		FOX, A. D., "Reduction of the Severity of Enterocolitis by Glutamine-Supplemented Enteral Diets", <u>Surgical Forum</u> , 38, (1987), 43-44	
		JACOBS, D. O., "Combined Effects of Glutamine and Epidermal Growth Factor on the Rat Intestine", <u>Surgery</u> , 104(2), (1988), 358-364	
		JACOBS, D. O., "Disparate Effects Of 5-Fluorouracil On The Ileum And Colon Of Enterally Fed Rats With Protection By Dietary Glutamine", <u>Surgical Forum</u> , 38, (1987), 45-46	
		KLIMBERG, V. S., "Oral Glutamine Accelerates Healing of the Small Intestine and Improves Outcome After Whole Abdominal Radiation", <u>Archives of Surgery</u> , 125(8), (1990), 1040-1045	
		KLIMBERG, V. S., "Prophylactic Glutamine Protects the Intestinal Mucosa from Radiation Injury", <u>Cancer</u> , 66(1), (1990), 62-68	
		MOORE, F. A., "TEN Versus TPN Following Major Abdominal Trauma - Reduced Septic Morbidity", <u>The Journal of Trauma</u> , 29(7), (1989), 916-923	
		O'DWYER, S. T., "5-Fluorouracil Toxicity on Small Intestinal Mucosa But Not White Blood Cells is Decreased by Glutamine", <u>Clinical Research</u> , 35(3), (1987), Page 369A	
		O'DWYER, S. T., et al., "Chapter 28 - New Fuels for the Gut", In: <u>Clinical Nutrition - Enteral and Tube Feeding</u> , 2nd Edition, Rombeau, J. L., et al., editors, W. B. Saunders Company, (1990), 540-555	
		PARRY-BILLINGS, M., "Does Glutamine Contribute to Immunosuppression After Major Burns?", <u>The Lancet</u> , 336(8714), (1990), 523-525	
		ROMBEAU, J. L., "A Review of the Effects of Glutamine-Enriched Diets on Experimentally Induced Enterocolitis", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(4) (Supp), (1990), 100S-105S	
		SCHLOERB, P. R., et al., "Total Parenteral Nutrition With Glutamine in Bone Marrow Transplantation and Other Clinical Applications (A Randomized, Double-Blind Study)", <u>Journal of Parenteral and Enteral Nutrition</u> , 17, 5, (1993), 407-413	
		SHOU, J., "Dietary Manipulation of Methotrexate-Induced Enterocolitis", <u>Journal of Parenteral & Enteral Nutrition</u> , 15(3), (1991), 307-312	
ICW		SMITH, R. J., "Glutamine Nutrition and Requirements", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(4) (Supp), (1990), 94S-99S	

EXAMINER

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Substitute Disclosure Statement Form (PTO-1449)

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K		SOUBA, W. W., "Glutamine Nutrition in the Management of Radiation Enteritis", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(4) (Supp), (1990),106S-108S	
		SOUBA, W. W., "Glutamine Nutrition: Theoretical Considerations and Therapeutic Impact", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(5) (Supp), (1990),237S-243S	
		SOUBA, W. W., "Intestinal Consumption of Intravenously Administered Fuels", <u>Journal of Parenteral & Enteral Nutrition</u> , 9(1), (1985),18-22	
		SOUBA, W. W., "Oral Gutamine Reduces Bacterial Translocation Following Abdominal Radiation", <u>Journal of Surgical Research</u> , 48(1), (1990),1-5	
		SOUBA, W. W., "The Gut as a Nitrogen-Processing Organ in the Metabolic Response to Critical Illness", <u>Nutrition Support Services</u> , 8, (1988),15-22	
		STEIGER, E., "Effects of Nutrition on Tumor Growth and Tolerance to Chemotherapy", <u>Journal of Surgical Research</u> , 18(4), (1975),455-66	
		VAN ZAAANEN, H. C. T., et al., "Parenteral Glutamine Dipeptide Supplementation Does Not Ameliorate Chemotherapy-Induced Toxicity", <u>Cancer</u> , 74(10), (1994),2879-2884	
		VANDERHOOF, J. A., "Effects of Oral Supplementation of Glutamine on Small Intestinal Mucosal Mass Following Resection", <u>Journal of the American College of Nutrition</u> , 11(2), (1992),223-227	
		WELLS, C. L., "The Effect of Dietary Glutamine and Dietary RNA on Ileal Flora, Ileal Histology, and Bacterial Translocation in Mice", <u>Nutrition</u> , 6(1), (1990),70-83	
		WINDMUELLER, H. G., "Glutamine Utilization by the Small Intestine", <u>Advances in Enzymology & Related Areas of Molecular Biology</u> , 53, (1982),201-37	
		WINDMUELLER, H. G., "Intestinal Metabolism of Glutamine and Glutamate from the Lumen as Compared to Glutamine from Blood", <u>Archives of Biochemistry & Biophysics</u> , 171(2), (1975),662-672	
		WINDMUELLER, H. G., "Respiratory Fuels and Nitrogen Metabolism <i>In Vivo</i> in Small Intestine of Fed Rats. Quantitative importance of glutamine, glutamate, and aspartate", <u>Journal of Biological Chemistry</u> , 255(1), (1980),107-112	
		ZIEGLER, T. R., "Clinical and Metabolic Efficacy of Glutamine-Supplemented Parenteral Nutrition After Bone Marrow Transplantation. A Randomized, Double-Blind, Controlled Study", <u>Annals of Internal Medicine</u> , 116(10), (1992),821-828	
W		ZIEGLER, T. R., "Safety and Metabolic Effects of L-Glutamine Administration in Humans", <u>Journal of Parenteral & Enteral Nutrition</u> , 14(4 Suppl), (1990), 137S-146S	

EXAMINER

DATE CONSIDERED

4-22-05